1 2 3 4 5 6 7 8 UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON 9 SEATTLE DIVISION 10 11 BENJAMIN DRESNER, Individually and On Behalf of All Others Similarly Situated, Case No. 2:21-CV-1499 12 Plaintiff, 13 **CLASS ACTION COMPLAINT** 14 v. 15 SILVERBACK THERAPEUTICS, INC., LAURA K. SHAWVER, JONATHAN 16 PIAZZA, RUSS HAWKINSON, PETER THOMPSON, VICKIE L. CAPPS, 17 ROBERT HERSHBERG, SAQIB ISLAM, JURY TRIAL DEMANDED ANDREW POWELL, JONATHAN ROOT, 18 THILO SCHROEDER, and SCOTT 19 PLATSHON, 20 Defendants. 21 22 23 24 25 26 27 28 **CLASS ACTION COMPLAINT - 1** 

Plaintiff Benjamin Dresner ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Silverback Therapeutics, Inc. ("Silverback" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

- 1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired: (a) Silverback common stock pursuant and/or traceable to the Offering Documents (defined below) issued in connection with the Company's initial public offering conducted on or about December 3, 2020 (the "IPO" or "Offering"); and/or (b) Silverback securities between December 3, 2020 and September 10, 2021, both dates inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act").
- 2. Silverback, a clinical-stage biopharmaceutical company, develops tissue-targeted therapeutics for the treatment of cancer, chronic viral infections, and other serious diseases. The Company's lead product candidate is SBT6050, which is in a Phase I/Ib clinical trial, a TLR8

agonist linker-payload conjugated to a HER2-directed monoclonal antibody that targets tumors, such as breast, gastric, and non-small cell lung cancers.

- 3. On November 10, 2020, Silverback filed a registration statement on Form S-1 with the SEC in connection with the IPO, which, after several amendments, was declared effective by the SEC on December 3, 2020 (the "Registration Statement").
- 4. On or about December 3, 2020, pursuant to the Registration Statement, Silverback's common stock began trading on the Nasdaq Global Market ("NASDAQ") under the ticker symbol "SBTX." On December 4, 2020, Silverback filed a prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement (the "Prospectus" and, together with the Registration Statement, the "Offering Documents").
- 5. Pursuant to the Offering Documents, Silverback conducted the IPO, issuing 11.5 million shares of common stock priced at \$21.00 per share.
- 6. The Offering Documents were negligently prepared and, as a result, contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading and were not prepared in accordance with the rules and regulations governing their preparation. Additionally, throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, the Offering Documents and Defendants made false and/or misleading statements and/or failed to disclose that: (i) Silverback's lead product candidate SBT6050 was less effective than the Company had represented to investors; (ii) accordingly, the Company had overstated SBT6050's commercial and/or clinical prospects; and (iii) as a result,

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the Offering Documents and Defendants' public statements throughout the Class Period were materially false and/or misleading and failed to state information required to be stated therein.

- 7. On September 13, 2021, Silverback issued a press release "announc[ing] that interim data from the dose-escalation portion of its Phase 1/1b clinical trial evaluating SBT6050 as a monotherapy and in combination with pembrolizumab in patients with advanced or metastatic HER2-expressing or amplified solid tumors will be presented at the upcoming European Society for Medical Oncology (ESMO) 2021 Congress from September 16-21, 2021" and advising that "[t]he accepted abstract . . . is now available on the ESMO website." Per the accepted abstract (the "Abstract"), while there was a manageable safety profile for the Company's experimental therapy, SBT6050 yielded only one partial response among 14 HER2-positive solid tumors.
- 8. On this news, Silverback's stock price fell \$4.54 per share, or 23.35%, to close at \$14.90 per share on September 13, 2021.
- 9. As of the time this Complaint was filed, the price of Silverback common stock continues to trade below the \$21.00 per share Offering price, damaging investors.
- 10. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Silverback's securities, Plaintiff and other Class members have suffered significant losses and damages.

## **JURISDICTION AND VENUE**

11. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o), and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

- 12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).
- 13. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Silverback is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.
- 14. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

## **PARTIES**

- 15. Plaintiff, as set forth in the attached Certification, purchased or otherwise acquired Silverback common stock pursuant and/or traceable to the Offering Documents issued in connection with the IPO, and/or purchased or otherwise acquired Silverback securities at artificially inflated prices during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.
- 16. Defendant Silverback is a Delaware corporation with principal executive offices located at 500 Fairview Ave N, Suite 600, Seattle, Washington 98109. The Company's common stock trades in an efficient market on the NASDAQ under the ticker symbol "SBTX."

- 17. Defendant Laura K. Shawver ("Shawver") has served as Silverback's Chief Executive Officer and as a Director at all relevant times. Shawver signed or authorized the signing of the Registration Statement filed with the SEC.
- 18. Defendant Jonathan Piazza ("Piazza") has served as Silverback's Chief Financial Officer at all relevant times. Piazza signed or authorized the signing of the Registration Statement filed with the SEC.
- 19. Defendants Shawver and Piazza are sometimes referred to herein collectively as the "Exchange Act Individual Defendants."
- 20. The Exchange Act Individual Defendants possessed the power and authority to control the contents of Silverback's SEC filings, press releases, and other market communications. The Exchange Act Individual Defendants were provided with copies of Silverback's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Silverback, and their access to material information available to them but not to the public, the Exchange Act Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Exchange Act Individual Defendants are liable for the false statements and omissions pleaded herein.
- 21. Silverback and the Exchange Act Individual Defendants are sometimes referred to herein collectively as the "Exchange Act Defendants."

- 22. Defendant Russ Hawkinson ("Hawkinson") has served as Senior Vice President of Finance of Silverback at all relevant times. Hawkinson signed or authorized the signing of the Registration Statement filed with the SEC.
- 23. Defendant Peter Thompson ("Thompson") has served as Silverback's Chairman of the Board of Directors at all relevant times. Thompson signed or authorized the signing of the Registration Statement filed with the SEC.
- 24. Defendant Vickie L. Capps ("Capps") served as a Director of the Company at the time of the IPO. Capps signed or authorized the signing of the Registration Statement filed with the SEC.
- 25. Defendant Robert Hershberg ("Hershberg") served as a Director of the Company at the time of the IPO. Hershberg signed or authorized the signing of the Registration Statement filed with the SEC.
- 26. Defendant Saqib Islam ("Islam") served as a Director of the Company at the time of the IPO. Islam signed or authorized the signing of the Registration Statement filed with the SEC.
- 27. Defendant Andrew Powell ("Powell") served as a Director of the Company at the time of the IPO. Powell signed or authorized the signing of the Registration Statement filed with the SEC.
- 28. Defendant Jonathan Root ("Root") served as a Director of the Company at the time of the IPO. Root signed or authorized the signing of the Registration Statement filed with the SEC.

- 29. Defendant Thilo Schroeder ("Schroeder") served as a Director of the Company at the time of the IPO. Schroeder signed or authorized the signing of the Registration Statement filed with the SEC.
- 30. Defendant Scott Platshon ("Platshon") served as a Director of the Company at the time of the IPO. Platshon signed or authorized the signing of the Registration Statement filed with the SEC.
- 31. The Exchange Act Individual Defendants and Defendants Hawkinson, Thompson, Capps, Hershberg, Islam, Powell, Root, Schroeder, and Platshon are sometimes referred to herein collectively as the "Securities Act Individual Defendants."
- 32. As directors, executive officers and/or major shareholders of the Company, the Securities Act Individual Defendants participated in the solicitation and sale of Silverback common stock in the IPO for their own benefit and the benefit of Silverback. The Securities Act Individual Defendants were key members of the IPO working group and executives of Silverback who pitched investors to purchase the shares sold in the IPO, including in IPO road shows.
- 33. Silverback and the Securities Act Individual Defendants are sometimes referred to herein collectively as the "Securities Act Defendants."
- 34. The Exchange Act Defendants and the Securities Act Defendants are sometimes collectively, in whole or in part, referred to herein as the "Defendants."

## SUBSTANTIVE ALLEGATIONS

# **Background**

35. Silverback, a clinical-stage biopharmaceutical company, develops tissue targeted therapeutics for the treatment of cancer, chronic viral infections, and other serious diseases. The

Company's lead product candidate is SBT6050, which is in a Phase I/Ib clinical trial, a TLR8 agonist linker-payload conjugated to a HER2-directed monoclonal antibody that targets tumors, such as breast, gastric, and non-small cell lung cancers.

- 36. On November 10, 2020, Silverback filed a registration statement on Form S-1 with the SEC in connection with the IPO, which, after several amendments, was declared effective by the SEC on December 3, 2020.
- 37. On or about December 3, 2020, pursuant to the Registration Statement, Silverback's common stock began trading on the NASDAQ under the ticker symbol "SBTX." On December 4, 2020, Silverback filed a prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement.
- 38. Pursuant to the Offering Documents, Silverback conducted the IPO, issuing 11.5 million shares of common stock priced at \$21.00 per share.

# Materially False and Misleading Statements Issued in the Offering Documents

39. In providing an overview of the Company, the Offering Documents, stated, in relevant part:

Our platform enables us to strategically pair proprietary linker-payloads that modulate key disease-modifying pathways with monoclonal antibodies directed to specific disease sites. Initially, we are applying our platform to create a new class of targeted immuno-oncology agents that direct a myeloid cell activator to the tumor microenvironment (TME) in solid tumors to promote cancer cell killing. Our lead product candidate, SBT6050, is comprised of a TLR8 agonist linker-payload conjugated to a HER2-directed monoclonal antibody that targets tumors such as certain breast, gastric and non-small cell lung cancers. SBT6050 is currently in a Phase 1/1b clinical trial as monotherapy and in combination with pembrolizumab, in patients with advanced or metastatic HER2-expressing solid tumors. In this trial, we have observed changes in pharmacodynamic markers in the first dose cohort, and we anticipate providing an update on interim data from the Phase 1 dose-escalation cohorts in the second half of 2021.

40. Next, in discussing the Company's development pipeline, the Offering Documents stated, in relevant part:

#### SBT6050

Our lead product candidate, SBT6050, is comprised of a TLR8 agonist linker-payload conjugated to a HER2-directed monoclonal antibody and is designed to activate myeloid cells in tumors expressing moderate to high levels of HER2. TLR8 is expressed in myeloid cell types prevalent in human tumors and TLR8 agonism can activate a broad spectrum of anti-tumor immune mechanisms. Therefore, we believe that TLR8 is the optimal target for activating human myeloid cell types in the TME.

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SBT6050 utilizes HER2 to localize and facilitate the delivery of the TLR8 agonist conjugate into myeloid cells in the TME. Therefore, unlike HER2 targeted therapies that have been approved by the U.S. Food and Drug Administration (FDA) such as Herceptin (trastuzumab), SBT6050 does not require HER2 to be an oncogenic driver to elicit anti-tumor activity. Furthermore, SBT6050 recognizes the HER2 sub-domain II, the pertuzumab epitope, and does not cross-block trastuzumab, allowing for potential combinations with trastuzumab-based agents, which are standard of care therapies in some HER2-expressing cancers.

We are currently evaluating the safety and tolerability of SBT6050 in a Phase 1 dose-escalation trial in patients with advanced or metastatic HER2-expressing solid tumors. As further described in the section titled "Business—Lead Product Candidate SBT6050: TLR8 Agonist Conjugated to a HER2 Antibody," the trial consists of four parts: monotherapy dose-escalation and expansion (Part 1), monotherapy dose expansion in tumor-specific cohorts (Part 2), pembrolizumab combination dose-escalation (Part 3), and a pembrolizumab combination dose expansion cohort (Part 4). Changes in pharmacodynamic markers have been observed in the first dose-escalation cohort of this trial. We anticipate providing an update on interim data from the Phase 1 dose-escalation cohorts in the second half of 2021.

41. Further, in discussing the Company's strategy, the Offering Documents stated, in relevant part:

Our goal is to transform the treatment of cancer and other serious diseases with unmet need using our ImmunoTAC platform to deliver a new class of systemically delivered, tissue-directed, and locally active therapies. The key elements of our business strategy are to:

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- Advance SBT6050 through clinical development in late-stage disease that may allow us to seek expedited approval using regulatory pathways available from the FDA such as Accelerated Approval, Breakthrough Therapy, Priority Review or Fast Track designation. In early clinical trials, we will be examining the anti-tumor activity of SBT6050 in patients that have failed all available therapies associated with clinical benefit, in addition to measuring biomarkers of immune cell activation. This approach may allow us to seek expedited approval from the FDA based on surrogate endpoints (through the Accelerated Approval path) and expedited FDA review through programs such as Breakthrough Therapy, Priority Review, or Fast Track designation. We are evaluating activity broadly across HER2-expressing cancer types, including cancers where no HER2-directed therapies are currently approved, and have identified several tumor types and lines of therapy that potentially present opportunities for utilizing one or more of these accelerated approval pathways.
- Advance SBT6050 subsequently into earlier lines of therapy to maximize patient benefit and commercial success, if approved. Our long-term clinical development goal is to position SBT6050 in early-line standard of care regimens in key indications to potentially provide benefit to patients. We seek to accomplish this by evaluating combination therapy approaches with therapeutics approved as standard of care. We believe SBT6050 has the potential to be an ideal combination therapy in early line settings.

(Emphasis in original.)

- 42. Finally, in describing the addressable market of SBT6050, the Offering Documents stated, in relevant part:
  - [. . .] HER2 IHC 2+ and 3+ overexpression and amplification are documented in at least 11 different tumor types including breast (estimated 83,000), gastric (estimated 6,400), non-small cell lung (estimated 31,500), colorectal (estimated 9,000), bladder (estimated 7,500), uterine (estimated 11,000), pancreatic (estimated 4,000), head and neck (estimated 2,000), ovarian (estimated 1,100), esophageal (estimated 3,000), and biliary (estimated 3,000) cancers, providing the potential to address a large HER2-expressing tumor agnostic market estimated to be more than 160,000 newly-diagnosed patients annually in the United States based in part on estimated prevalence rates. HER2 IHC2+ and 3+ overexpression in breast cancer, gastric cancer, and NSCLC are 30.0%, 16.4%, and 23.2%, respectively. Most HER2 targeted therapies require the tumor cells to be dependent on HER2 signaling, often called an oncogenic driver. HER2 oncogenic-driven tumors are limited to subsets of breast and gastric cancer and hence the FDA-approved therapies that require HER2 signaling are limited to

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these indications as noted in the figure. SBT6050 does not require the tumor cells to be dependent on HER2 signaling for its anti-tumor activity and instead utilizes the HER2 protein to deliver the conjugate to adjacent myeloid cells. We believe that this expands the market opportunity beyond HER2-driven breast and gastric cancer in which targeted HER2 agents have been approved and are established as standard of care. Because of the rationale to combine SBT6050 with CPI's, which is supported by our preclinical data [...]

(Emphasis added.)

43. The statements referenced in ¶¶ 39-42 were materially false and misleading because the Offering Documents were negligently prepared and, as a result, contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading and were not prepared in accordance with the rules and regulations governing their preparation. Specifically, the Offering Documents made false and/or misleading statements and/or failed to disclose that: (i) Silverback's lead product candidate SBT6050 was less effective than the Company had represented to investors; (ii) accordingly, the Company had overstated SBT6050's commercial and/or clinical prospects; and (iii) as a result, the Offering Documents were materially false and/or misleading and failed to state information required to be stated therein.

# Materially False and Misleading Statements Issued During the Class Period

- 44. The Class Period begins on December 3, 2020, when Silverback's securities began publicly trading on the NASDAQ pursuant to the materially false or misleading statements or omissions in the Offering Documents, as referenced in  $\P\P$  39-42, *supra*.
- 45. On March 29, 2021, Silverback filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2020 (the "2020 10-K"). In providing an overview of the Company, the 2020 10-K stated, in relevant part:

Our platform enables us to strategically pair proprietary linker-payloads that

modulate key disease-modifying pathways with monoclonal antibodies directed to

specific disease sites. Initially, we are applying our platform to create a new class

of targeted immuno-oncology agents that direct a myeloid cell activator to the tumor microenvironment (TME) in solid tumors to promote cancer cell killing. Our lead product candidate, SBT6050, is comprised of a TLR8 agonist linker-payload conjugated to a HER2-directed monoclonal antibody that targets tumors such as certain breast, gastric and non-small cell lung cancers. SBT6050 is currently in a Phase 1/1b clinical trial as a monotherapy and in combination with pembrolizumab, in patients with advanced or metastatic HER2-expressing solid tumors. In this trial, we have observed changes in pharmacodynamic markers in the first dose cohort, and we anticipate providing an update on interim data from the Phase 1 single agent dose-escalation cohorts in the second half of 2021.

46. Next, in discussing the Company's development pipeline, the 2020 10-K stated,

in relevant part:

## SBT6050

Our lead product candidate, SBT6050, is comprised of a TLR8 agonist linker-payload conjugated to a HER2-directed monoclonal antibody and is designed to activate myeloid cells in tumors expressing moderate to high levels of HER2. TLR8 is expressed in myeloid cell types prevalent in human tumors and TLR8 agonism can activate a broad spectrum of anti-tumor immune mechanisms. Therefore, we believe that TLR8 is the optimal target for activating human myeloid cell types in the TME.

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SBT6050 utilizes HER2 to localize and facilitate the delivery of the TLR8 agonist conjugate into myeloid cells in the TME. Therefore, unlike HER2 targeted therapies that have been approved by the U.S. Food and Drug Administration (FDA) such as Herceptin (trastuzumab), SBT6050 does not require HER2 to be an oncogenic driver to elicit anti-tumor activity. Furthermore, SBT6050 recognizes the HER2 sub-domain II, the pertuzumab epitope, and does not cross-block trastuzumab, allowing for potential combinations with trastuzumab-based agents, which are standard of care therapies in some HER2-expressing cancers.

We are currently evaluating the safety and tolerability of SBT6050 in a Phase 1 dose-escalation trial in patients with advanced or metastatic HER2-expressing solid tumors. Changes in pharmacodynamic markers have been observed in the first dose-escalation cohort of this trial. We anticipate providing an update on interim data from the Phase 1 single agent dose-escalation cohorts in the second half of 2021.

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47. Further, in discussing the Company's strategy, the 2020 10-K stated, in relevant

Our goal is to transform the treatment of cancer and other serious diseases with unmet need using our ImmunoTAC platform to deliver a new class of systemically delivered, tissue-directed, and locally active therapies. The key elements of our business strategy are to:

- Advance SBT6050 through clinical development in late-stage disease that may allow us to seek expedited approval using regulatory pathways available from the FDA such as Accelerated Approval, Breakthrough Therapy, Priority Review or Fast Track designation. In early clinical trials, we will be examining the anti-tumor activity of SBT6050 in patients that have failed all available therapies associated with clinical benefit, in addition to measuring biomarkers of immune cell activation. This approach may allow us to seek expedited approval from the FDA based on surrogate endpoints (through the Accelerated Approval path) and expedited FDA review through programs such as Breakthrough Therapy, Priority Review, or Fast Track designation. We are evaluating activity broadly across HER2-expressing cancer types, including cancers where no HER2-directed therapies are currently approved, and have identified several tumor types and lines of therapy that potentially present opportunities for utilizing one or more of these accelerated approval pathways.
- Advance SBT6050 subsequently into earlier lines of therapy to maximize patient benefit and commercial success, if approved. Our long-term clinical development goal is to position SBT6050 in early-line standard of care regimens in key indications to potentially provide benefit to patients. We seek to accomplish this by evaluating combination therapy approaches with therapeutics approved as standard of care. We believe SBT6050 has the potential to be an ideal combination therapy in early line settings.

(Emphasis in original.)

- 48. Finally, in discussing SBT6050's addressable market, the 2020 10-K stated, in relevant part:
  - [...] HER2 IHC 2+ and 3+ overexpression and amplification are documented in at least 11 different tumor types including breast (estimated 83,000), gastric (estimated 6,400), non-small cell lung (estimated 31,500), colorectal (estimated 9,000), bladder (estimated 7,500), uterine (estimated 11,000), pancreatic (estimated 4,000), head and neck (estimated 2,000), ovarian (estimated 1,100),

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esophageal (estimated 3,000), and biliary (estimated 3,000) cancers, providing the potential to address a large HER2-expressing tumor agnostic market estimated to be more than 160,000 newly-diagnosed patients annually in the United States based in part on estimated prevalence rates. HER2 IHC2+ and 3+ overexpression in breast cancer, gastric cancer, and NSCLC are 30.0%, 16.4%, and 23.2%, respectively. Most HER2 targeted therapies require the tumor cells to be dependent on HER2 signaling, often called an oncogenic driver. HER2 oncogenic-driven tumors are limited to subsets of breast and gastric cancer and hence the FDA-approved therapies that require HER2 signaling are limited to these indications as noted in the figure. SBT6050 does not require the tumor cells to be dependent on HER2 signaling for its anti-tumor activity and instead utilizes the HER2 protein to deliver the conjugate to adjacent myeloid cells. We believe that this expands the market opportunity beyond HER2-driven breast and gastric cancer in which targeted HER2 agents have been approved and are established as standard of care. Because of the rationale to combine SBT6050 with CPI's, which is supported by our preclinical data [...]

(Emphasis added.)

- 49. Appended to the 2020 10-K as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 by Defendants Shawver and Piazza, attesting that, "[t]he information contained in the [2020 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."
- 50. Corresponding with the 2020 10-K, Silverback issued a press release announcing the Company's Q4 and full year 2020 financial results and recent corporate updates. The press release stated, in relevant part:

"2020 was an extraordinary year for Silverback, with the initiation of our first clinical study for SBT6050, in which pharmacological activity was observed in the first dose cohort, the advancement of each of our preclinical programs, expansion of our strong team, and the successful closing of our IPO in December," said Laura Shawver, Ph.D., chief executive officer of Silverback. "We are well-positioned to execute on our mission to develop a new class of tissue-localized therapies that are designed to modulate fundamental biological pathways in cancer and beyond."

# 2020 Corporate Highlights and 2021 Anticipated Milestones

• SBT6050 (HER2-TLR8 ImmunoTAC) Phase 1/1b clinical study initiated, with pharmacological activity demonstrated in the first dose

**cohort.** SBT6050 is being studied as a monotherapy and in combination with pembrolizumab, in patients with advanced or metastatic HER2-expressing solid tumors. Changes in pharmacodynamic markers consistent with the potential mechanism of action have been observed in patients treated in the first monotherapy dose cohort. Enrollment is ongoing in Part 1 of the study (SBT6050 monotherapy dose escalation) and treatment has been initiated in Part 3 of the study (SBT6050 plus pembrolizumab dose-escalation). Silverback is on track to deliver interim clinical data from Part 1 of the study in the second half of 2021.

51. On May 13, 2021, Silverback issued a press release announcing the Company's Q1 2021 financial results. The press release stated, in relevant part:

"In our first quarter as a public company, our team continues to execute on Silverback's mission to bring tissue-targeted therapies to patients in need," said Laura Shawver, Ph.D., chief executive officer of Silverback. "We are on track to report interim clinical data for SBT6050 in the second half of this year, and we are equally excited about the progress and preclinical data emerging from SBT6290 and SBT8230, highlighting the broad applicability of our ImmunoTAC platform."

## **Recent Highlights**

- SBT6050 (HER2-TLR8 ImmunoTAC) continues to advance through monotherapy and pembrolizumab combination dose escalation arms of the Phase 1/1b clinical study. Silverback is on track to deliver interim clinical data from the monotherapy dose escalation arm of the study in the second half of 2021.
- 52. On July 7, 2021, Silverback issued a press release entitled, "Silverback Therapeutics Announces Clinical Supply Agreement with Regeneron to Evaluate SBT6050 in Combination with Libtayo® (cemiplimab), initially in HER2-expressing Non-Small Cell Lung and Gastric Cancers." The press release stated, in relevant part:

Silverback [...] today announced a clinical supply agreement with Regeneron for Libtayo® (cemiplimab). The supply agreement supports the evaluation of Libtayo®, a PD-1 inhibitor, in combination with SBT6050, the first of a new class of targeted immuno-oncology agents designed to direct a TLR8 agonist linker-payload to activate myeloid cells in tumors expressing moderate to high levels of HER2.

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"SBT6050's unique ability to activate both innate and adaptive immune responses has the potential to enhance and expand the effectiveness of a PD-1 inhibitor in HER2-expressing solid tumors," said Naomi Hunder, M.D., Chief Medical Officer of Silverback. "We are eager to complete the ongoing dose escalation of SBT6050 combined with a PD-1 inhibitor, and look forward to working with Regeneron as we begin tumor-specific expansion cohorts."

In the first quarter of 2021, Silverback initiated treatment in Part 3 of the Phase 1/1b study to evaluate the activity of SBT6050 in combination with a PD-1 inhibitor in dose escalation. Under the terms of the agreement, Silverback will expand the ongoing Phase 1/1b trial to evaluate the combination of SBT6050 and Libtayo® in tumor-specific dose expansion cohorts, initially in HER2-expressing non small cell lung cancer [...] and gastric cancer.

On August 12, 2021, Silverback issued a press release announcing the 53. Company's Q2 2021 financial results and providing a business update. The press release stated, in relevant part:

"The second quarter was notable for the significant progress we made across our entire pipeline of tissue-targeted therapies, with SBT6050, our HER2-TLR8 ImmunoTAC leading the way with continued robust enrollment in our Phase 1/1b study," said Laura Shawver, Ph.D., chief executive officer of Silverback. "We are deeply appreciative of the patients, their families, and our clinical investigators who continue to contribute to the SBT6050-101 clinical trial, and we look forward to providing the first update of the clinical data at the ESMO conference in September."

54. The statements referenced in ¶¶ 44-53 were materially false and misleading because the Exchange Act Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, the Exchange Act Defendants made false and/or misleading statements and/or failed to disclose that: (i) Silverback's lead product candidate SBT6050 was less effective than the Company had represented to investors; (ii) accordingly, the Company had overstated SBT6050's commercial and/or clinical prospects; and (iii) as a result, Defendants' public statements throughout the Class Period were materially false and/or misleading and failed to state information required to be stated therein.

#### **The Truth Emerges**

55. On September 13, 2021, Silverback issued a press release "announc[ing] that interim data from the dose-escalation portion of its Phase 1/1b clinical trial evaluating SBT6050 as a monotherapy and in combination with pembrolizumab in patients with advanced or metastatic HER2-expressing or amplified solid tumors will be presented at the upcoming European Society for Medical Oncology (ESMO) 2021 Congress from September 16-21, 2021" and advising that "[t]he accepted abstract . . . is now available on the ESMO website." Per the Abstract, while there was a manageable safety profile for the Company's experimental therapy, SBT6050 yielded only one partial response among 14 HER2-positive solid tumors. Specifically, the Abstract stated, in relevant part:

#### **Results**

As of 4 April 2021, 18 patients across 10 tumor types were treated at 4 dose levels (Part 1, n=14; Part 3, n=4). Dose levels of SBT6050 ranging from 0.15 mg/kg to 1.2 mg/kg were pharmacologically active as demonstrated by the induction of blood-based biomarkers associated with myeloid cell and NK or T cell activation. SBT6050 exposures up to 0.6 mg/kg increase greater than dose-proportionally, and linear thereafter, reflecting evidence of target saturation at 0.6 mg/kg. Furthermore, increases in IFNγ, a marker for NK and/or T cell activation, along with additional on-target biomarkers, plateaued at 0.6 mg/kg. The most frequent (>25%) related TEAEs were chills, diarrhea, fatigue, hypotension, injection site reaction, nausea, pyrexia, and vomiting. Dose levels >0.6 mg/kg were evaluated to assess the upper limits of the dose range; Grade 3 DLTs that resolved with supportive care were observed in Part 1 at 1.2 mg/kg Q2 weeks. *In response-evaluable patients* (N=14), best overall response was PR (n=1), SD (n=3), and PD (n=10).

#### **Conclusions**

Based on preliminary safety data, SBT6050 given alone or in combination with pembrolizumab has a manageable safety profile. Related TEAEs are consistent with immune activation. A single-agent dose of 0.6 mg/kg administered Q2 weeks had a tolerable safety profile, drug exposure that reflects evidence of target saturation, and pharmacodynamics indicative of myeloid, NK and T cell activation.

(Emphasis added).

- 56. On this news, Silverback's stock price fell \$4.54 per share, or 23.35%, to close at \$14.90 per share on September 13, 2021.
- 57. As of the time this Complaint was filed, the price of Silverback common stock continues to trade below the \$21.00 per share Offering price, damaging investors.
- 58. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Silverback's securities, Plaintiff and other Class members have suffered significant losses and damages.

## PLAINTIFF'S CLASS ACTION ALLEGATIONS

- 59. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired: (a) Silverback common stock in the IPO or purchased Silverback common stock thereafter in the stock market pursuant and/or traceable to the Company's Offering Documents issued in connection with the IPO; or (b) Silverback securities during the Class Period; and were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.
- 60. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Silverback securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class

may be identified from records maintained by Silverback or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

- 61. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 62. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 63. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
  - whether the federal securities laws were violated by Defendants' acts as alleged herein;
  - whether statements made by Defendants to the investing public in the Offering Documents for the IPO, or during the Class Period, misrepresented material facts about the business, operations and management of Silverback;
  - whether the Securities Act Individual Defendants negligently prepared the Offering Documents for the IPO and, as a result, the Offering Documents contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading, and were not prepared in accordance with the rules and regulations governing their preparation;
  - whether the Exchange Act Individual Defendants caused Silverback to issue false and misleading financial statements during the Class Period;
  - whether certain Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
  - whether the prices of Silverback securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

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- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 64. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.
- 65. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:
  - Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
  - the omissions and misrepresentations were material;
  - Silverback securities are traded in an efficient market;
  - the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
  - the Company traded on the NASDAQ and was covered by multiple analysts;
  - the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
  - Plaintiff and members of the Class purchased, acquired and/or sold Silverback securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.
- 66. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.
- 67. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State*

of Utah v. United States, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

## **COUNT I**

# (Violations of Section 11 of the Securities Act Against the Securities Act Defendants)

- 68. Plaintiff repeats and incorporates each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.
- 69. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of the Class, against the Securities Act Defendants.
- 70. The Offering Documents for the IPO were inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.
- 71. Silverback is the registrant for the IPO. The Securities Act Defendants named herein were responsible for the contents and dissemination of the Offering Documents.
- 72. As issuer of the shares, Silverback is strictly liable to Plaintiff and the Class for the misstatements and omissions in the Offering Documents.
- 73. None of the Securities Act Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Documents were true and without omissions of any material facts and were not misleading.
- 74. By reasons of the conduct herein alleged, each Securities Act Defendant violated, and/or controlled a person who violated Section 11 of the Securities Act.

- 75. Plaintiff acquired Silverback shares pursuant and/or traceable to the Offering Documents for the IPO.
- 76. Plaintiff and the Class have sustained damages. The value of Silverback common stock has declined substantially subsequent to and because of the Securities Act Defendants' violations.

## **COUNT II**

# (Violations of Section 15 of the Securities Act Against the Securities Act Individual Defendants)

- 77. Plaintiff repeats and incorporates each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.
- 78. This Count is asserted against the Securities Act Individual Defendants and is based upon Section 15 of the Securities Act, 15 U.S.C. § 77o.
- 79. The Securities Act Individual Defendants, by virtue of their offices, directorship, and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Silverback within the meaning of Section 15 of the Securities Act. The Securities Act Individual Defendants had the power and influence and exercised the same to cause Silverback to engage in the acts described herein.
- 80. The Securities Act Individual Defendants' positions made them privy to and provided them with actual knowledge of the material facts concealed from Plaintiff and the Class.
- 81. By virtue of the conduct alleged herein, the Securities Act Individual Defendants are liable for the aforesaid wrongful conduct and are liable to Plaintiff and the Class for damages suffered.

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#### **COUNT III**

# (Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against the Exchange Act Defendants)

- 82. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.
- 83. This Count is asserted against the Exchange Act Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.
- 84. During the Class Period, the Exchange Act Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Silverback securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Silverback securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, the Exchange Act Defendants, and each of them, took the actions set forth herein.
- 85. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Exchange Act Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents

described above, including statements made to securities analysts and the media that were designed to influence the market for Silverback securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Silverback's finances and business prospects.

- 86. By virtue of their positions at Silverback, the Exchange Act Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Exchange Act Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to the Exchange Act Defendants. Said acts and omissions of the Exchange Act Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Exchange Act Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.
- 87. Information showing that the Exchange Act Defendants acted knowingly or with reckless disregard for the truth is peculiarly within the Exchange Act Defendants' knowledge and control. As the senior managers and/or directors of Silverback, the Exchange Act Individual Defendants had knowledge of the details of Silverback's internal affairs.
- 88. The Exchange Act Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Exchange Act Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Silverback. As officers and/or directors of a publicly-held company, the Exchange Act Individual Defendants had a duty to disseminate timely, accurate, and truthful

information with respect to Silverback's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Silverback securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Silverback's business and financial condition which were concealed by the Exchange Act Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Silverback securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by the Exchange Act Defendants, and were damaged thereby.

89. During the Class Period, Silverback securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Exchange Act Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Silverback securities at prices artificially inflated by the Exchange Act Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Silverback securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Silverback securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

90. By reason of the conduct alleged herein, the Exchange Act Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

91. As a direct and proximate result of the Exchange Act Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

## **COUNT IV**

# (Violations of Section 20(a) of the Exchange Act Against the Exchange Act Individual Defendants)

- 92. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.
- 93. During the Class Period, the Exchange Act Individual Defendants participated in the operation and management of Silverback, and conducted and participated, directly and indirectly, in the conduct of Silverback's business affairs. Because of their senior positions, they knew the adverse non-public information about Silverback's misstatement of income and expenses and false financial statements.
- 94. As officers and/or directors of a publicly owned company, the Exchange Act Individual Defendants had a duty to disseminate accurate and truthful information with respect to Silverback's financial condition and results of operations, and to correct promptly any public statements issued by Silverback which had become materially false or misleading.
- 95. Because of their positions of control and authority as senior officers, the Exchange Act Individual Defendants were able to, and did, control the contents of the various

reports, press releases and public filings which Silverback disseminated in the marketplace during the Class Period concerning Silverback's results of operations. Throughout the Class Period, the Exchange Act Individual Defendants exercised their power and authority to cause Silverback to engage in the wrongful acts complained of herein. The Exchange Act Individual Defendants therefore, were "controlling persons" of Silverback within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Silverback securities.

- 96. Each of the Exchange Act Individual Defendants, therefore, acted as a controlling person of Silverback. By reason of their senior management positions and/or being directors of Silverback, each of the Exchange Act Individual Defendants had the power to direct the actions of, and exercised the same to cause, Silverback to engage in the unlawful acts and conduct complained of herein. Each of the Exchange Act Individual Defendants exercised control over the general operations of Silverback and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.
- 97. By reason of the above conduct, the Exchange Act Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Silverback.

#### PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

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1	В.	Requiring Defendants to	pay damages sustained by Plaintiff and the Class by
2	reason of the acts and transactions alleged herein;		
3	C. Awarding Plaintiff and the other members of the Class prejudgment and post-		
4	judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and		
5			
6	D. Awarding such other and further relief as this Court may deem just and proper.		
7	DEMAND FOR TRIAL BY JURY		
8	Plaintiff hereby demands a trial by jury.		
9			
10	DATED this 5 <sup>th</sup> day of November, 2021		
11			
12			BADGLEY MULLINS TURNER PLLC
13			/s/ Duncan C. Turner
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